REMARKS

Claims 1, 14-20, 22-30, 36-38, 41, 117-122, and 124-136 are pending in the application. Claims 2-13, 21, 31-35, 39-40, 42-116, and 123 have been cancelled in prior Replies without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file continuation applications directed to the subject matter of any claim cancelled for any reason.

I. Rejection of Claims 1, 14-15, 18-20, 22-30, 36-38, 41, 117-120, 122, and 124-136 under 35 U.S.C. § 103(a) over Riley in view of Wakat

The Examiner maintains the rejection of claims 1, 14-15, 18-20, 22-30, 36-38, 41, 117-120, 122, and 124-136 under 35 U.S.C. § 103(a). Paper No. 19 at page 2. Specifically, the Examiner alleges that these claims are "unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128) for the reasons set forth in the prior office action." *Id.* Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

Applicants assert that the Examiner has failed to establish a *prima facie* case of obviousness because (1) the references, singly or in combination, fail to teach or suggest each and every element of the claimed invention, (2) there is no teaching, suggestion or motivation that can be derived from the references of record to combine the teachings of the references, and (3) the primary reference teaches away from the claimed formulations.

The Examiner must show that the prior art references of record teach or suggest the claimed invention. Riley, in combination with Wakat, fails to teach or suggest each and every element of independent claims 1, 37, 117, and 134. Specifically, the Examiner admits, "Riley

does not teach expressly that the amount of folic acid is at least about 800 mcg, or the particular amounts range of each and every ingredients." Paper No. 15 at page 2. The attention of the Examiner is respectfully directed to the fact that the compositions of independent claim 1 comprises at least 800 mcg of folic acid and claims 37, 117, and 134 comprise about 2.25 mg to about 2.75 mg of folic acid.

The Examiner alleges Riley teaches "the nutritional composition comprising up to 800 mcg of folic acid [and] Wakat teaches that folic acid as a nutritional supplement may be in the range of 300 mcg to 10 mg," concluding "that it would have been prima facie obvious to employ more than 800 mcg of folic acid in Riley's nutritional composition." Paper No. 19 at page 4. Applicants assert that the Examiner has failed to show the requisite suggestion, teaching, or motivation in the references of record to combine the alleged teachings of Riley and the alleged teachings of Wakat to produce the compositions defined by any one of independent claim 1, independent claim 37, independent claim 117, and independent claim 134. Therefore, Applicants assert that the Examiner's rejection based upon a *prima facie* case of obviousness is improper. *In re Rouffet*, 149 F.3d 1350,1357, 47 U.S.P.Q.2d 1453, 1457-58 (Fed. Cir. 1998)(stating that if the combination of references teach every element of the claimed invention ***without a motivation to combine***, then a rejection based upon a *prima facie* case of obviousness is improper)(emphasis added).

Riley teaches that synergistic interrelationships exist between the vitamins and minerals contained in the formulations and that increasing the dosage of one nutrient, may affect the absorption or utilization of another vitamin or mineral within the same formulation. For example, Riley states:

> [T]he formulas avoid excessive beta-carotene, which may negatively effect the activity of alpha-tocopherol (vitamin E). This effect has been taken into account in the formulations by providing appropriate doses. The formulas utilize water-soluble vitamin E, which do not require dietary lipids for absorption. The inclusion of Q-10, as a facilitator of vitamin E is a useful and unique advantage of this formulation. The limitation of excess copper in the formula helps prevent the negative effects of copper, which can oppose the antioxidant action of vitamin E.

Riley at column 20, lines 24-35.

> The Module 1 formulation is based on the concept that increasing the dosage of one nutrient may affect the absorption or utilization of another vitamin or mineral. For example, one function of vitamin C is to facilitate iron absorption...vitamin D is essential for calcium absorption...[V]itamin A and E metabolically interact...Moreover, the dosage of one nutrient, if not physiologically appropriate, may change the requirement of another nutrient and even impair the immune response.

Id. at column 11, lines 20-33.

In addition to a requirement for the appropriate levels of vitamins and minerals, Riley teaches that the formulations must also contain the appropriate combinations of vitamins and minerals. For example, Riley states:

> The Module 1 formulation, see Tables II and III, provides a nutritional supplement that contributes to increased health and active life span by insuring optimal intake of nutrients in ***appropriate levels*** and ***combinations*** to insure protection against nutritional losses and deficiencies due to lifestyle factors and common inadequate dietary patterns while optimizing defenses of protective nutrients and compounds which may decrease risk of chronic diseases, such as cited above.

Id. at column 8, lines 21-30 (emphasis added).

Notably, in the prior office action (Paper No. 15), the Examiner selectively picked in support of the rejection, without the requisite teaching or suggestion, thirteen of the thirty-five micronutrients separately listed in claim 1 of Riley, and thirteen of the thirty-three micronutrients separately listed in Table II and III of Riley. Paper No. 15 at page 2. The Examiner then selectively picked, without the requisite teaching or suggestion, one of the thirteen micronutrients separately listed in, for example, claim 3 of Wakat to combine with Riley to arrive at the claimed formulations. *Id.* at pages 2-3. Applicants assert that modifying the combination of vitamins and minerals of Riley's formulation as stated by the Examiner would render Riley's formulations ineffective for its intended purpose as stated by Riley.

Indeed, Applicants submit that if the formulation of Riley was modified (as the Examiner proposes) to contain greater than 800 mcg of folic acid, then this modification would render

Riley's formulation ineffective for its intended use. Accordingly, if the proposed modifications render the prior art invention being modified unsatisfactorily for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984).

Applicants maintain that the Examiner cannot pick and choose from the primary and secondary references, in hindsight reconstruction, the specific elements of the composition of the present invention to create an obviousness rejection. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). Riley explicitly teaches that any deletion, addition, and/or substitution of any of the vitamins or minerals disclosed in the formulations would affect the absorption or utilization of another vitamin, and thus, would render the formulations ineffective for their intended purpose. Moreover, any modification to the disclosed doses of vitamins and minerals would affect the absorption or utilization of another vitamin, and thus, would render the formulations ineffective for their intended purpose.

The Examiner's position that "optimization of the amounts of active ingredients in a nutrient or therapeutical composition is within the skill of the artisan"(Paper No. 19 at pages 2-3) is unsupportable in view of the express prohibition of the same by Riley. Therefore, since the Examiner's proposed modifications to Riley's formulation would, in Riley's own words, render the formulations ineffective, the requisite motivation or suggestion to combine the teachings of Riley with the teachings of Wakat does not exist.

Indeed, the Examiner makes no *prima facie* case of obviousness. Accordingly, the claimed compositions would not have been obvious in view of the cited references of record and Applicants respectfully request that the present rejection of claims 1, 14-15, 18-20, 36-38, 41, 117-120, 122 and 124-136 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

II. Rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) over Riley in view of Wakat and in further view of McLeod

The Examiner maintains the rejection of claims 16 and 17 under 35 U.S.C. § 103(a) as "being unpatentable over Riley in view of Wakat and in further view of McLeod." Paper No. 19 at page 2. Applicants respectfully traverse.

Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully

assert that the present rejection should be withdrawn because the Examiner's *prima facie* obviousness rejection is improper. As discussed above, Applicants assert that (1) the references of record, singly or in combination, fail to teach each and every element of the claimed invention, (2) there is no teaching, suggestion or motivation that can be derived from the references of record to combine the teachings of the references, and (3) Riley teaches away from modifying the folic acid amount to be greater than 800 mcg. Therefore, Applicants respectfully request that the present rejection of claims 16 and 17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

III. Rejection of Claim 121 under 35 U.S.C. § 103(a) over Riley in view of Wakat and in further view of Anderson

The Examiner maintains the rejection of claim 121 under 35 U.S.C. § 103(a) as "being unpatentable over Riley in view of Wakat and in further view of Anderson." *Id.* Applicants respectfully traverse.

Without addressing the propriety of the Examiner's rejection, and specifically the Examiner's interpretation of what the cited references teach or suggest, Applicants respectfully submit that the present rejection should be withdrawn because the Examiner's *prima facie* obviousness rejection is improper. As discussed above, Applicants assert that (1) the references of record, singly or in combination, fail to teach each and every element of the claimed invention, (2) there is no teaching, suggestion or motivation that can be derived from the references of record to combine the teachings of the references, and (3) Riley teaches away from modifying the folic acid amount to be greater than 800 mcg. Therefore, Applicants respectfully request that the present rejection of claim 121 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

IV. CONCLUSION

Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. In addition, filed concurrently herewith is a request for Examiner's interview.

If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

13 November 2003

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Applicant Initiated Interview Request Form

Application No.: 09/671283 First Named Applicant: John A. GIORDANO
Examiner: Shengjun WANG Art Unit: 1617 Status of Application: Reply filed 13 November 2003

Tentative Participants:
(1) Don J. Pelto (2) Examiner Shengjun Wang

(3) Andrea D. Tiglio, Ph.D. (4)_____

Proposed Date of Interview: Tuesday, December 2, 2003 **Proposed Time:** 11:00 AM

Type of Interview Requested:
(1) [ ] Telephonic (2) [X] Personal (3) [ ] Video Conference

Exhibit to Be Shown or Demonstrated: [ ] YES [X] NO
If yes, provide brief description:_____

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1)_____	_____	_____	[ ]	[ ]	[ ]
(2)_____	_____	_____	[ ]	[ ]	[ ]
(3)_____	_____	_____	[ ]	[ ]	[ ]
(4)_____	_____	_____	[ ]	[ ]	[ ]

[ ] Continuation Sheet Attached

Brief Description of Arguments to be Presented:
Discussion of Section 103 Rejection of Claims

An interview was conducted on the above-identified application on _____.

NOTE:
This form should be completed by applicant and submitted to the examiner in advance of the interview (see MPEP § 713.01). This application will not be delayed from issue because of applicant's failure to submit a written record of this interview. Therefore, application is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible.

(Applicant/Applicant's Representative Signature) (Examiner/SPE Signature)
Don J. Pelto, Reg. No. 33,754 11/13/03